HHS Extends PREP Act Immunity to COVID-19 Countermeasures

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The U.S. Department of Health and Human Services issued a declaration (the "Declaration") under the Public Readiness and Emergency Preparedness Act (the "PREP Act") to protect "Covered Persons" from liability in relation to the manufacture, distribution, or administration of "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product" (or "Covered Countermeasures"). Covered Persons include manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as well as certain additional persons connected to the administration of the Covered Countermeasures.

To qualify for protection under the Declaration, Covered Countermeasures must also be "'qualified pandemic or epidemic products,' or 'security countermeasures,' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act." Examples of the types of liability covered under the Declaration include claims alleging negligence against a manufacturer in connection with the development of a vaccine, negligence claims against a healthcare provider for prescribing the wrong dose of a Covered Countermeasure, and claims relating to the management and operation of a site where Covered Countermeasures are stored, shipped, transported, or offered for sale (e.g., a slip-and-fall injury or vehicle collision). The Declaration does not, however, provide immunity from liability arising from willful misconduct. The Declaration is retroactively effective as of February 4, 2020 and provides protection through October 1, 2025. See the Declaration for more information.

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